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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/687,177  | 10/16/2003  | Naomi L. Nakao       | G30-016             | 7585             |
| R. Neil Sudol 7590 11/07/2008<br>714 Colorado Avenue<br>Bridgeport, CT 06605-1601 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| KASZTEJNA, MATTHEW JOHN   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3739  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 11/07/2008  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/687,177

**Applicant(s)**

NAKAO, NAOMI L.

**Examiner**

MATTHEW J. KASZTEJNA

**Art Unit**

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 July 2008.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,10,12,13,15-21,30,31 and 45-49 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1,3,10,12,13,15-21,30,31 and 45-49 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 30 January 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-849)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Notice of Amendment***

In response to the amendment filed July 31, 2008, amended claims 1, 10 and 15 are acknowledged. The following new and reiterated grounds of rejection are set forth:

***Specification***

The amendment filed July 31, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: paragraph 0034 - Insertion shaft 10 *inseparably* includes a longitudinally extending illumination guide 20 and a longitudinally extending image guide 22. The invention previously failed to require an illumination guide and image guide as being *inseparable* from the endoscope insertion shaft.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 10 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. The amendments stating "inseparably incorporating an image-carrying component or image guide" are considered new matter. Furthermore, paragraph 0034 - Insertion shaft 10 *inseparably* includes a longitudinally extending illumination guide 20 and a longitudinally extending image guide 22. The invention previously failed to require an illumination guide and image guide as being *inseparable* from the endoscope insertion shaft. Applicant states the amendments to claims 1 and 15 are not new matter, "inasmuch as one skilled in the art understands full well that conventional flexible endoscopes have inseparable image guides". Examiner disagrees. It is not well known in the art to incorporate an inseparable image guide within an endoscope. Many conventional endoscopes have interchangeable optical systems and thus the image guides are not inseparable (see class 600/172). Thus, it is well known within the endoscopic that it is often a desirable trait to have image-carrying components which are separable from the endoscope shaft for the purposes of cleaning and/or interchanging optical systems. Virtually all conventional endoscopes *do not* have inseparable image or illumination guides as suggested by the applicant.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 10, 12-13, 15-21, 30-31 and 45-49 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,840,013 to Lee et al.

**In regards to claim 1**, Lee et al. disclose an apparatus comprising a flexible elongate insertion shaft 1238 inseparably incorporating an image guide, the insertion shaft is formed having an outer surface with at least one longitudinally extending channel 1246 having a first transverse dimension or diameter, the channel having a longitudinally extending slot (i.e. upper edge of legs 1243a-b) through the outer surface, the slot having a second transverse dimension or width, the second transverse dimension or width being smaller than the first transverse dimension or diameter (see Fig. 14), further comprising at least one closure member 1230 removably connected to the insertion shaft to close the slot, the insertion shaft being formed with a pair of opposing edges along the slot, the closure member being removably attached to the insertion shaft at the edges, the closure member being an elongate strip removably attached to the insertion shaft at the edges, the closure member being provided with guide channels 1252 and the shaft being provided with protrusions 1292 insertable into the guides (see Col. 17, Lines 3-22). **In regard to claims 10 and 30-31**, Lee et al. disclose an entrainment element 92 for facilitating manipulation, to slide closure member along the slot (see Col. 10, Lines 44-55).

**In regards to claim 3**, Lee et al. disclose an apparatus wherein said channel has a distal end opening and proximal end opening, said slot extending from said distal end opening to said proximal end opening, said closure member closing said slot while

maintaining said distal end opening and said proximal end opening unobstructed (see Figs. 1 and 12).

**In regards to claims 12-13 and 15**, Lee et al. disclose a flexible endoscope, further comprising a catheter disposed in the channel (see Fig. 22 and Col. 8, Lines 33-36 and Col. 18, Lines 59-67).

**In regards to claim 16**, Lee et al. disclose an apparatus, wherein the catheter is provided at a proximal end with connectors for coupling the catheter to a source of irrigation fluid 308 and a source of suction 310 (see Figs. 11a-j and Col. 15, Lines 20-30).

**In regards to claims 17-19**, Lee et al. disclose an apparatus, wherein at a proximal end the channel terminates at an entry port bifurcated with respect to and diverging from the shaft, further comprising a biopsy channel liner removably disposed in the channel and extending at a proximal end out of the entry port, an end cap being fitted to the liner at the entry port (see Figs. 12, 17-21 and 23 and Col. 19, Lines 18-60).

**In regards to claim 20**, Lee et al. disclose an apparatus, wherein the channel extends from a proximal end portion of the insertion shaft to a distal tip thereof (see Fig. 1).

**In regards to claim 21**, Lee et al. disclose an apparatus, wherein the channel has a mostly circular cross-section divided by the slot, the channel being defined by a surface of the insertion member having a C-shaped cross-section (see Col. 8, Lines 24-28).

**In regards to claims 45-46**, Lee et al. disclose an apparatus, wherein the insertion shaft has a first outer surface and the closure member has a second outer surface, the second outer surface being smoothly continuous with the first outer surface (see Fig. 14).

**In regards to claims 47-48**, Lee et al. disclose an apparatus, wherein the closure member is attached to the insertion shaft only along the edges of the slot (see Fig. 14).

**In regards to claims 49**, Lee et al. disclose an apparatus, wherein the closure member is separate from and independent from the catheter (see Fig. 22 Col. 18, Lines 59-67).

Claims 1, 3, 10, 12-13, 15, 30-31 and 45-49 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,616,603 to Fontana.

**In regards to claims 1, 15**, Fontana discloses an apparatus comprising a flexible elongate insertion shaft 2 inseparably incorporating an image-carrying component 7, the insertion shaft is formed having an outer surface with at least one longitudinally extending channel 1b having a first transverse dimension or diameter, the channel having a longitudinally extending slot 11 through the outer surface, the slot having a second transverse dimension or width, the second transverse dimension or width being smaller than the first transverse dimension or diameter (see Figs 4-6), further comprising at least one closure member 6 removably connected to the insertion shaft to close the slot, the insertion shaft being formed with a pair of opposing edges along the slot, the closure member being removably attached to the insertion shaft at

the edges, the closure member being an elongate strip removably attached to the insertion shaft at the edges, at least one of the closure member and the shaft being provided with grooves and the other being insertable within the groove (see Col. 3, Lines 1-50). **In regard to claims 10 and 30-31**, Fontana discloses an entrainment element 5 for facilitating manipulation, to slide closure member along the slot (see Fig. 4).

**In regards to claim 3**, Fontana discloses an apparatus wherein said channel has a distal end opening and proximal end opening, said slot extending from said distal end opening to said proximal end opening, said closure member closing said slot while maintaining said distal end opening and said proximal end opening unobstructed (see Figs. 4-6).

**In regards to claims 12-13, 15 and 49**, Fontana discloses a flexible endoscope, fully capable of comprising a catheter disposed in the channel (see Col. 3, Lines 13-15).

**In regards to claims 45-46**, Fontana discloses an apparatus, wherein the insertion shaft has a first outer surface and the closure member has a second outer surface, the second outer surface being smoothly continuous with the first outer surface (see Fig. 6).

**In regards to claims 47-48**, Fontana discloses an apparatus, wherein the closure member is attached to the insertion shaft only along the edges of the slot (see Fig. 6).



***Response to Arguments***

Applicant's arguments filed July 31, 2008 have been fully considered but they are not persuasive.

Applicant states that neither Lee nor Fontana discloses an endoscope that is integrally provided with an open or slotted working channel. Examiner disagrees. The term integral by definition means: of, pertaining to, or belonging as a part of the whole; constituent or component (see <http://dictionary.reference.com/browse/integral>). Thus both Lee and Fontana clearly disclose an endoscope having an insertion shaft provided with an open or slotted working channel as discussed in the rejection above.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., wherein the channels are in the endoscope shaft itself) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, Lee discloses an endoscope comprising an elongate insertion shaft 1238 inseparably incorporating an "image guide" 1292 (see Fig 14). In the broadest interpretation of the claim, the term "image guide" is simply the space in which the endoscope is held. The channel itself acts as the image guide as the slot, comprised of guide channels 1252 can not be removed (see Col. 16, Lines 55-64). Thus, as broadly as claimed, Lee discloses an endoscope comprising an elongate insertion shaft inseparably incorporating an image guide.

Additionally, Fontana discloses an endoscope comprising an elongate insertion shaft 2 inseparably incorporating an image carry-component 7 (see Fig. 1 and Col.2, Lines 52-55). The wall 7 is provided with a reflective surface in order to reflect the light beam from source 6 in cavity 1b and through said opening 3, and to reflect the image of the field of view that is being inspected. Thus, as broadly as claimed, Fontana meets the limitation of the recited claims.

Alternatively, Applicant's arguments with respect to claims 1, 3, 10, 12-13, 15-21, 30-31 and 45-49 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./  
Examiner, Art Unit 3739

/Linda C Dvorak/  
Supervisory Patent Examiner, Art  
Unit 3739

10/29/8